Overview of Title VII and FDA's Approach to Implementation

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Public Meeting: Implementation of Drug Supply Chain Provisions of Title VII of FDASIA
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Title VII: What it Does

Increases FDA's ability to:

701, 702, 703, 704, 713, 714, 715

- Collect and analyze data to enable risk-informed decision-making

705, 706

- Advance risk-based approach to facility oversight – part of broader shift towards more strategic, risk-based approach to regulation and enforcement

710, 712

- Partner with foreign regulatory authorities to leverage resources through information-sharing and recognition of foreign inspections

707, 708, 709, 711, 716, 717, 718

- Drive safety and quality throughout the supply chain through strengthened tools

Collect and Analyze Data to Enable Risk-Informed Decision-Making

Section	Summary
701 & 702	Registration of foreign and domestic facilities • U.S. and foreign drug establishments must provide Unique Facility Identifier (UFI) so FDA knows where establishments are located
703	Identification of drug excipient information with product listing • Listing for a drug is to include name, address, and UFI for manufacturers of excipients used in that drug
704	Electronic registration and listing system • Ensure our drug registration and listing databases contain accurate, complete information and can interface with other relevant agency databases
713	Standards for admission of imported drugs • Shift burden of proof at the border and require importer to show compliance
714	Registration of commercial importers • Require commercial importers to register with FDA • Prescribe “good importer practices”
715	Notification • Require manufacturers, importers, distributors to notify FDA when drugs threaten serious injury/death or are lost/stolen/counterfeit

Advance Risk-Based Approaches to Facility Oversight

Section	Summary
705	Risk-based inspection frequency • Eliminates minimum inspection frequency requirement for domestic drug establishments • Requires FDA to target both domestic and foreign inspections on the basis of risk
706	Records for inspection • Allows FDA to request and obtain records – electronically or in physical form – in advance or in lieu of an inspection

Partner with Foreign Regulatory Authorities

Section	Summary
710	Exchange of information • Allows FDA, under certain conditions, to exchange information with peer regulators globally
712	Recognition of foreign government inspections • Allows FDA to recognize foreign inspections • Foreign inspection results can be used to facilitate risk-based inspection, as evidence of compliance with cGMPs and import standards, and for any other “appropriate” purposes

Drive Safety and Quality Through Strengthened Tools

Section	Summary
707	Delaying, denying, limiting or refusing inspection • Makes adulterated any drug that has been manufactured, processed, packed or held in a facility that has stymied FDA inspection
708	Destruction • Addresses problem of illegal products at international mail facilities • With due process, allows FDA to destroy drugs refused entry into the U.S.
709	Administrative detention • Allows FDA to administratively detain drugs • Already had this authority for tobacco, food, and devices
711	Enhancing safety and quality • Requires manufacturers to adopt quality management systems as part of cGMP
716 & 717	Enhanced penalties for counterfeiting and intentional adulteration
718	Extraterritorial jurisdiction • Intended to ensure that FDA can enforce FD&C Act outside the U.S

Title VII Implementation Challenges

- Numerous, significant deliverables
  - Estimating at least:
    - 5 Regulations
    - 3 Guidances
    - 1 Annual Report
- Significant operational changes: new or modified Agency systems, policies, and procedures
- Other major statutory implementations also occurring: FSMA, GDUFA, etc.
- No funding provided

Title VII Implementation Strategy

- Prioritizing deliverables based on public health impact
- Work groups focusing on individual sections, with management structure to help streamline and expedite
- Engaging with stakeholders to build awareness and support, and gain input
  - Dockets
  - Public meetings
  - Website

Title VII: Management and Oversight Structure

Title VII Implementation: Accomplishments to Date

- Increased penalties for counterfeiting and adulteration (Sections 716 - 717)
- Issued draft guidance on delaying, denying, limiting or refusing inspection (Section 707)
  - Failure to comply with records request under Section 706 may constitute violation of Section 707 in certain circumstances
- Issued proposed regulation on administrative detention (Section 709)
  - Mirrors device authority and regulation
- https://www.federalregister.gov/public-inspection

Summary

- Title VII provides important new authorities that advance FDA's global strategy, and FDA is working diligently to implement them
- Implementation is challenging and resource-intensive
- FDA will work to provide transparency and opportunities for input throughout
  - Updates posted through FDASIA TRACK on FDA website

Thank You!

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